

OCT 16 1985

JOSEPH F. SPANIOLO, JR.
CLERK

14
No. 85-619

IN THE
SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1985

MERRELL DCW PHARMACEUTICALS, INC.,
Petitioner,

vs.

LARRY JAMES CHRISTOPHER THOMPSON AND
DONNA LYNN THOMPSON AS NEXT FRIENDS AND
GUARDIANS OF JESSICA ELIZABETH THOMPSON,
LARRY JAMES CHRISTOPHER THOMPSON,
INDIVIDUALLY AND DONNA LYNN THOMPSON,
INDIVIDUALLY, *et al.*,

Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the
Sixth Circuit

JOINT APPENDIX

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Petition for Certiorari filed October 11, 1985
Certiorari Granted December 2, 1985

631P

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RELEVANT DOCKET ENTRIES

**UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT**

Case No. 84-3418

Appeal from the Southern District of Ohio,
Western Division, at Cincinnati

**LARRY JAMES CHRISTOPHER THOMPSON and
DONNA LYNN THOMPSON, as guardians of
Jessica Elizabeth Thompson, a minor;
LARRY JAMES CHRISTOPHER THOMPSON and
DONNA LYNN THOMPSON, Individually;
NEIL FRAZER MacTAVISH and
MARGARET MacTAVISH as guardians of Neil MacTavish;
NEIL FRAZER MacTAVISH and
MARGARET MacTAVISH, Individually,
Plaintiffs-Appellants,
vs.
MERRELL DOW PHARMACEUTICALS, INC., fka
RICHARDSON MERRELL, INC.,
Defendants-Appellees.**

Date
1984

06/01 Copy Notice of Appeal, filed; and cause docketed.

06/06 Certified Record, (2 vol. of pleadings)

Date
1984

06/26 Notice from court reporter, Kuppin, transcript unnecessary for appeal purposes.

08/09 Certified Supplemental Record, (1 vol. of pleadings)

11/20 Brief (10) of appellant (m-11/20)

12/20 Brief (10) of appellee (m-12/20)

Date
1985

01/07 REPLY BRIEF (10) Appellant (m-01/07)

01/10 JOINT APPENDIX (5) (Vols. I, II, III) [84-3366/3418/39/95/3796]

01/14 CERTIFIED SUPPLEMENTAL RECORD (01 vol. pleadings), filed [84-3366/3418/39/95/3796]

02/01 MOTION appellee to file supplement to joint appendix and correct index pages in original appendix (m-02/01) [84-3366/3418 3439/3495/3796] (Motion Granted, JPH/kmp, per jst, 2/5)

02/01 SUPPLEMENTAL JOINT APPENDIX (5) (m-02-01) and filed 2/5

03/07 ADDITIONAL CITATIONS by appellant (m-03/05)

03/15 ADDITIONAL CITATIONS by appellee (Woodside) (m-03/14)

07/15 JUDGMENT of the District Court is reversed and the case is remanded with instructions, appellants to recover costs from appellee (Jones, Krupansky and Hull, JJ.)

Date
1985

07/15 OPINION by Jones, J.

10/21 NOTICE of filing petition for certiorari (S. Ct. No. 85-619) 10/11/85

RELEVANT DOCKET ENTRIES

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO, WESTERN DIVISION

83-1436 Thompson v. MDL

Date

09-08-83 PETITION FOR REMOVAL from Hamilton Co.
Cthse — attached are the following COM-
PLAINT, JURY DEMAND
* * *

10-14-83 MOTION TO REMAND UNDER § 1447(c) for
Lack of Juris, by pltf.

10-31-83 MEMO IN OPP (979), by deft.

11-22-83 REPLY IN SUPPORT (979), by pltf.

12-21-83 MOTION TO DISMISS ON GROUNDS OF
FORUM NON CONVENIENS, BY DEFT.
* * *

01-24-84 MEMO OPP (1132), by pltf.

02-08-84 REPLY IN SUPPORT (1132), by deft.
* * *

05-14-84 ORDER DENYING PLTF'S Motion to remand
(979) and GRANTING deft's motion to dismiss on
forum non conveniens (1132) CMTc LC/WOOD-
SIDE

05-14-84 JUDGMENT ENTRY ON DECISION OF
COURT (1676) JS-6 submitted

05-18-84 ACCEPTANCE OF CONDITIONS OF ORDER
OF JUDGMENT OF DISMISSAL by deft.

05-22-84 NOTICE OF APPEAL by pltf from judgment of
5-14-84.

05-30-84 Sent Pleadings #1677-1711-1718 to COFA.
(Copies) & 1676 (m)

06-04-84 Acknowledge Receipt from COFA Their No.
84-3418 (m)

RELEVANT DOCKET ENTRIES

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO, WESTERN DIVISION

83-1437 MacTavish v. MDL

Date

09-08-83 PETITION FOR REMOVAL by deft. — Attached
are complaint & Jury demand
* * *

10-31-83 MEMO IN OPP (979), by deft.

11-22-83 REPLY IN SUPPORT (979), by pltf.

12-21-83 MOTION TO DISMISS ON GROUNDS OF
FORUM NON CONVENIENS, by deft.
* * *

01-24-84 MEMO OPP (1133), by pltf.

02-08-84 REPLY IN SUPPORT (1133), by deft
* * *

05-14-84 ORDER DENYING PLTF'S motion to remand
(979) and GRANTING deft's Motion to Dismiss on
forum non conveniens (1133) CMTc LC/WOOD-
SIDE

05-14-84 JUDGMENT ENTRY ON DECISION OF
COURT (1676) JS-6 submitted

05-18-84 ACCEPTANCE OF CONDITIONS OF ORDER
OF JUDGMENT OF DISMISSAL by deft.

05-22-84 NOTICE OF APPEAL by pltf from judgment of
5-14-84

05-30-84 Sent Pleadings #1678-1712-1718 to COFA. (copies)
(m)

UNITED STATE COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 84-3418

LARRY JAMES CHRISTOPHER THOMPSON, et al.,
Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., f/k/a
Richardson Merrell, Inc.,
Defendant-Appellee.

Before: JONES and KRUPANSKY, Circuit Judges; and
HULL, Chief District Judge.

JUDGMENT

[Filed July 15, 1985]

ON APPEAL from the United States District Court for the
Southern District of Ohio.

THIS CAUSE came on to be heard on the record from the
said District Court and was argued by counsel.

ON CONSIDERATION WHEREOF, It is now here
ordered and adjudged by this court that the judgment of the
said District Court in this case be and the same is hereby
reversed and the case is remanded with instructions consistent
with this opinion.

It is further ordered that Plaintiffs-Appellants recover from
Defendant-Appellee the costs on appeal, as itemized below,
and that execution therefor issue out of said District Court, if
necessary.

ENTERED BY ORDER OF THE
COURT

John P. Hehman, Clerk

/s/ JOHN P. HEHMAN,
Clerk

ISSUED AS AMENDED MANDATE: August 15, 1985
COSTS: Awarded to appellant)

Filing fee\$ 70.00
Printing\$332.50
Total\$402.50

A True Copy.

Attest:

/s/ GARY McCARTHY
Deputy Clerk

No. 84-3418

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUITLARRY JAMES CHRISTOPHER THOMP-
SON, et al.,*Plaintiffs-Appellants,*

v.

MERRELL DOW PHARMACEUTICALS,
INC.,*Defendant-Appellee.*ON APPEAL from the
United States District
Court for the South-
ern District of Ohio.

Decided and Filed July 15, 1985

Before: JONES and KRUPANSKY,^{*} Circuit Judges; and HULL,
Chief District Judge.*

JONES, Circuit Judge. This appeal presents the issue of whether actions filed in state court are properly removable to federal court if the complaints allege in part that the defendant violated the Food, Drug and Cosmetic Act and that this violation constituted "a rebuttable presumption of negligence." Plaintiffs-appellants contend that these cases presented no federal question upon which removal could be properly based. We agree and reverse and remand.

Plaintiffs-appellants, the Thompsons and the MacTavishes, are residents of Scotland and Canada respectively. They filed their complaints against defendant-appellee, Merrell Dow Pharmaceuticals, Inc., in the Court of Common Pleas, Hamilton County, Ohio. The complaints alleged that Mrs. Thompson and Mrs. MacTavish ingested Benedectin, a drug developed, produced, manufactured, and sold by Merrell

* Honorable Thomas G. Hull, District Judge, United States District Court for the Eastern District of Tennessee, sitting by designation.

Dow, and that the ingestion of the drug resulted in the birth defects suffered by both Jessica Thompson and Neil MacTavish. Each complaint alleged liability based upon the state-created theories of common law fraud, negligence, strict liability, and breach of warranty. They also alleged that Merrell Dow violated certain provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-392 (FDCA) and that those violations establish a rebuttable presumption of negligence. Pursuant to 28 U.S.C. § 1441, Merrell Dow removed these actions to the district court where they were consolidated. Plaintiffs filed a motion to remand under § 1447(c) for lack of subject matter jurisdiction. The district court denied plaintiffs' motion to remand and granted Merrell Dow's motion to dismiss on the ground of forum non conveniens. Appellants then filed this appeal.

Removal jurisdiction in a federal district court is premised upon 28 U.S.C. § 1441. Section 1441(a) provides for removal of actions generally, and § 1441(b) limits a defendant's ability to remove actions from a state court to situations where the defendant is not a citizen of the state in which such action is brought. Section 1441(c) permits a district court to determine all issues raised in an action when one claim, which would be removable if sued upon alone, is joined with one or more otherwise non-removable claims. The standard for determining when an action is removable is whether the court would have had jurisdiction, subject to the limitations of § 1441(b), if the action had been instituted originally in federal court under 28 U.S.A. § 1331 or § 1332. See *Franchise Tax Board v. Construction Laborers Vacation Trust*, 103 S. Ct. 2841, 2845 (1983). Consequently, a case removed to federal court under the guise of federal question jurisdiction presents a federal question when it "arises under" federal law. In *Franchise Tax Board*, the Court stated:

Under our interpretations, Congress has given the lower courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well pleaded complaint establishes either that federal law creates the

cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.

Id. at 2856.

The parties agree that the FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act. Federal question jurisdiction would, thus, exist only if plaintiffs' right to relief *depended necessarily* on a substantial question of federal law. Plaintiffs' causes of action referred to the FDCA merely as one available criterion for determining whether Merrell Dow was negligent. Because the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA, the plaintiffs' causes of action did not depend necessarily upon a question of federal law. Consequently, the causes of action did not arise under federal law and, therefore, were improperly removed to federal court. See *Zeig v. Shearson/American Express, Inc.*, 592 F. Supp. 612, 613-14 (E.D. Va. 1984); *State of Florida ex rel. Broward County*, 329 F. Supp. 364, 366 n.3 (S.D. Fla. 1971).

Accordingly, the judgment of the district court is REVERSED and the case is REMANDED with instructions to remand the cases to the Court of Common Pleas for Hamilton County, Ohio, where they were first filed.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO-WESTERN DIVISION

C-1-83-1436

LARRY JAMES CHRISTOPHER THOMPSON, et al.,
v.
MERRELL DOW PHARMACEUTICALS, INC.

Chief Judge Carl B. Rubin

Judgment
(Filed May 14, 1984)

* * *

Decision by Court. This action came to trial or hearing before the Court with the judge (magistrate) named above presiding. The issues have been tried or heard and a decision has been rendered.

IT IS ORDERED AND ADJUDGED
that plaintiff's Motion to Remand (Doc. No. 979) is hereby DENIED and defendant's Motion to Dismiss on *forum non conveniens* grounds (1132) is hereby GRANTED.

Clerk

KENNETH J. MURPHY

(By) Deputy Clerk

/s/ STEPHEN M. SNYDER

Date 5-14-84

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO-WESTERN DIVISION

C-1-83-1437

NEIL FRAZER MACTAVISH, et al.,
v.
MERRELL DOW PHARMACEUTICALS, INC.

Chief Judge Carl B. Rubin

Judgment
(Filed May 14, 1984)

* * *

Decision by Court. This action came to trial or hearing before the Court with the judge (magistrate) named above presiding. The issues have been tried or heard and a decision has been rendered.

IT IS ORDERED AND ADJUDGED

. . . that plaintiff's Motion to Remand (Doc. No. 979) is hereby DENIED and defendant's Motion to Dismiss on *forum non conveniens* grounds (1133) is hereby GRANTED.

Clerk

KENNETH J. MURPHY

(By) Deputy Clerk

/s/ STEPHEN M. SNYDER

Date 5-14-84

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

MDL #486

IN RE: RICHARDSON-MERRELL, INC.
"BENEDICTIN" PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATED TO:

THOMPSON	C-1-83-1436
MacTAVISH	C-1-83-1437

**ORDER DENYING PLAINTIFFS'
MOTION TO REMAND (Doc. No. 979)
AND GRANTING DEFENDANT'S
MOTIONS TO DISMISS ON
FORUM NON CONVENIENS GROUNDS**
(Doc. Nos. 1132, Thompson; 1133, MacTavish)
(Filed May 14, 1984)

This matter is before the Court on plaintiffs' Motion (Doc. No. 979) to remand the above-captioned cases to the Court of Common Pleas, Hamilton County, Ohio, and on defendant's Motions (Doc. Nos. 1132 and 1133) to dismiss on *forum non conveniens* grounds. For the reasons which follow, plaintiffs' Motion will be denied and defendant's Motions will be granted.

I. Motion to Remand

These cases were originally filed in the Court of Common Pleas, Hamilton County, Ohio, and removed by defendants to this Court pursuant to 28 U.S.C. § 1441. Removal was

premised on this Court's jurisdiction over cases "arising under the Constitution, treaties or laws of the United States." See 28 U.S.C. § 1441(b). See also 28 U.S.C. §§ 1441(a), 1331.¹ Plaintiffs subsequently filed their Motion to Remand, asserting that federal-question jurisdiction was lacking and that the case had been improvidently removed from state court.²

Specifically at issue is the fourth cause of action in each Complaint. That cause of action, used by defendant as the basis for removal, alleges negligence resulting from defendant's alleged failure to comply with the labeling provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("the Act"). After outlining pertinent provisions of the Act in Paragraphs 18 through 24 of each Complaint, plaintiffs set forth the following in Paragraphs 25 through 27:

25. That the promotion of said drug, Benedectin, by the defendant . . . constituted misbranding of said pharmaceutical drug per sub-sections (a), (f)(2) and (j) of § 502 and (u) of § 201 of [the Act].

26. That violation of said Federal Statutes in the promotion of said drug, Benedectin, by the Defendant herein enumerated, constitutes a rebuttable presumption of negligence.

27. That the Defendant's violation of said Federal Statutes directly and proximately caused the injuries suffered by [plaintiffs] . . .

The question facing the Court is whether plaintiffs' fourth cause of action states a claim "arising under" the laws of the United States.

In attempting to clarify the phrase "arising under," the Supreme Court has formulated definitions employing varying

¹ Section 1441(c) provides for the removal of an entire case if it contains at least one "separate and independent claim or cause of action, which would be removable if sued upon alone." The district court may, in its discretion, determine all the issues in the case or remand those not within its original jurisdiction.

² The parties agree that federal-question jurisdiction provides the only arguable basis for removal of these cases.

language. See, e.g., *Gully v. First National Bank*, 299 U.S. 109 (1936); *Moore v. Chesapeake & Ohio Ry.*, 291 U.S. 205 (1934); *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921); *American Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257 (1916).

Upon examination of the pertinent cases, this Court concludes that the definition set forth in *Smith*, *supra*, provides the appropriate standard for analysis. Cf., *T.B. Harms Co. v. Eliscu*, 339 F.2d 823, 827 (2nd Cir. 1964), *cert. denied*, 381 U.S. 915 (1965) (*Smith* was "path-breaking" opinion). See also *Franchise Tax Bd. v. Construction Laborers Vacation Trust*, ___ U.S. ___, 103 S.Ct. 2841, 2846 (1983).

In *Smith*, the Supreme Court stated the "general rule" as follows:

[W]here it appears from the bill or statement of the plaintiff that the right to relief depends upon the construction or application of the Constitution or laws of the United States, and that such federal claim is not merely colorable, and rests upon a reasonable foundation, the District Court has jurisdiction. . . .

Smith, *supra*, at 199.³

Applying the rule as stated in *Smith*, the Court concludes that federal-question jurisdiction exists over these cases and that they were properly removed. Although plaintiffs' fourth cause of action is technically a claim for negligence pursuant to state law, the sole basis for the claim is the alleged violation of the federal Act by defendant. Therefore, the key issue with respect to that cause of action is whether defendant's conduct violated the Act. Phrased in terms of the *Smith* standard, plaintiffs' "right to relief depends upon the . . . ap-

³ This Court recognizes that *Smith* is in apparent conflict with *Moore*, *supra*, and that the conflict appears, at first blush, to be irreconcilable. See, M. Redish, *Federal Jurisdiction*, 67 (1980). However, subsequent federal court decisions have reconciled and distinguished the two cases on the basis of the state statutory schemes involved in each. See *Abrams v. Citibank*, 537 F.Supp. 1192, 1196 (S.D. N.Y. 1982). The case at bar is analagous to *Smith* and therefore distinguishable from *Moore*.

plication of the . . . laws of the United States." *Smith, supra*, at 199. Accordingly, the Court holds that plaintiffs' fourth cause of action arises under the laws of the United States and that these cases were properly removed to federal court.⁴ Plaintiff's Motion to Remand will be denied.

II. Motions to Dismiss

The precise issues raised by defendant's Motions to Dismiss on *forum non conveniens* grounds have previously been considered by the Court under factual circumstances virtually identical with those at bar. See *order Granting Defendant's Motion to Dismiss in Vandervliet* (Doc. No. 1578) (facts virtually identical to *Thompson*); *In Re Richardson-Merrell, Inc.*, 545 F.Supp. 1130 (S.D. Ohio 1983), *aff'd. sub nom Dowling v. Richardson-Merrell, Inc.*, 727 F.2d 608 (6th Cir. 1984) (facts identical to *MacTavish*). Defendant's Motion with respect to *Thompson* will be granted for the reasons set forth in *Vandervliet, supra*, and defendant's Motion with respect to *MacTavish* will be granted for the reasons set forth in *In Re Richardson-Merrell, Inc., supra*. The granting of each of defendant's motions is subject to the five conditions set forth in *Dowling, supra*, at 611, 616.

Accordingly, for the reasons set forth above, and subject to the conditions noted, plaintiffs' Motion to Remand (Doc. No. 979) is hereby DENIED and defendant's Motions to Dismiss on *forum non conveniens* grounds (Doc. Nos. 1132 and 1133) are hereby GRANTED.

IT IS SO ORDERED.

/s/ CARL B. RUBIN, Chief Judge
United States District Court

⁴ In asserting a lack of federal-question jurisdiction, plaintiffs argue, *inter alia*, that jurisdiction is lacking because no private right of action exists under the Act. The Court is not impressed by this argument. This is not a situation where plaintiffs are seeking some form of relief under the Act itself.

COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO

Case No. A8307058

LARRY JAMES CHRISTOPHER THOMPSON and
DONNA LYNN THOMPSON as Next Friends and
Guardians of JESSICA ELIZABETH THOMPSON, A Minor
222 Church Street
Napanee, Ontario Canada K7R1C6

LARRY JAMES CHRISTOPHER THOMPSON, Individually
222 Church Street
Napanee, Ontario Canada K7R1C6

DONNA LYNN THOMPSON, Individually
222 Church Street
Napanee, Ontario Canada K7R1C6

Plaintiffs,

vs.

MERRELL-DOW PHARMACEUTICALS, INC.,
(formerly known as Richardson-Merrell, Inc.)
a Delaware Corporation
2110 East Galbraith Road
Cincinnati, Ohio 45215

Defendant.

COMPLAINT AND JURY DEMAND
[Filed September 1, 1983]

Now come the Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, and Individually, and state their causes of action as follows.

FIRST CAUSE OF ACTION

1. The Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as Next Best Friends and Guardians of Jessica Elizabeth Thompson, a Minor and Individually, state that they are residents of the City of Ontario, Country of Canada, Providence of Napanee.

2. That Defendant Merrell-Dow Pharmaceutical, Inc., FDBA Merrell-National Laboratories, Division of Richardson-Merrell, Inc., is a Delaware corporation with its principal place of business in the City of Cincinnati, County of Hamilton, State of Ohio.

3. That on or about December of 1978, Plaintiff Donna Lynn Thompson became pregnant with Jessica Elizabeth Thompson.

4. That during the first trimester of said pregnancy, Donna Lynn Thompson began to experience nausea for which her obstetrician prescribed the drug product known as Bendectin.

5. That said product, Bendectin, is a prescription drug made and distributed by the Defendant.

6. That Jessica Elizabeth Thompson was born September 21, 1979 subsequent to which it became obvious that the minor suffered from multiple deformities, including but not limited to, recto-vulvar fistula, anal atresia and sacral agenesis.

7. That as a result of said abnormalities, Jessica Elizabeth Thompson was caused to undergo extensive medical treatment and was and will continue to be required to undergo further medical treatment.

8. That the injuries suffered by Jessica Elizabeth Thompson were directly and proximately caused by the administration of the drug product Bendectin to Donna Lynn Thompson during the first trimester of pregnancy.

9. That the negligence of the Defendant in developing, marketing, producing, manufacturing, distributing and selling a product that Defendant knew or should have known could cause injuries and defects in children such as Jessica Elizabeth Thompson upon ingestion during pregnancy, directly and proximately caused said injuries; that the injuries

were directly and proximately caused by the negligence of the Defendant in failing to test or inadequately testing the potential birth defect producing effects upon ingestion of Bendectin during pregnancy; that injuries were caused, directly and proximately by the negligence of the Defendant in failing to warn the users of Bendectin of the potential birth defect producing effects upon ingestion during pregnancy.

10. That as a direct and proximate result of the aforementioned negligence of the Defendant, Jessica Elizabeth Thompson was and will be caused to suffer considerable pain and suffering and to undergo further medical treatment, and Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Larry James Christopher Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff, Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

SECOND CAUSE OF ACTION

11. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 10 and for their Second Cause of Action state as follows.

12. That Defendant expressly and impliedly warranted that its product, Bendectin, was of merchantable quality and fit and safe for its intended purposes and uses.

13. That Defendant breached said express and implied warranties of merchantability, fitness and safety and that said breach directly and proximately caused the injuries suffered by Jessica Elizabeth Thompson, a Minor, and that as a direct

and proximate breach of the aforementioned warranties, said Minor was and will be caused to suffer considerable pain and suffering, and to undergo continuous medical treatment, and Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson were and will be caused to suffer considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff, Larry James Christopher Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff, Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

THIRD CAUSE OF ACTION

14. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 13 and for their Third Cause of Action state as follows.

15. That Defendant is strictly liable in that it developed, marketed, produced, manufactured, distributed and sold an inherently dangerous and defective drug, to-wit Bendectin, which it knew or should have known could cause injuries and defects in children such as said Minor upon ingestion during pregnancy, while failing to test or inadequately testing the potential birth defect producing effects upon ingestion during pregnancy and failing to warn the users of Bendectin of the potential birth defect producing effects upon ingestion during pregnancy.

16. That the foregoing acts and omissions of the Defendant directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs,

Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Larry James Christopher Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

FOURTH CAUSE OF ACTION

17. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 16 and for their Fourth Cause of Action state as follows.

18. That the applicable Federal law covering the manufacturing and distributing of drugs during the time period in controversy was the Federal Food, Drug and Cosmetics Act passed by the 7th Congress on June 25, 1938, and cited as 52 Stat 1040, as amended.

19. That the purpose of 52 Stat 1040, among other purposes, was to prohibit the movement in Interstate Commerce of misbranded drugs.

20. That per § 201(n) of 52 Stat 1040, the determination as to whether a drug is misbranded includes "not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences, which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary and usual".

21. That Defendant did not at any time during the time period in controversy, reveal or attempt to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug in question for indications relating to pregnancy.

22. That pursuant to § 502(a) of 52 Stat 1040, a drug is deemed misbranded if its labeling is false or misleading in any particular.

23. That pursuant to § 502(f)(2) of 52 Stat 1040, a drug is deemed misbranded unless its labeling bears "such adequate warning against use in those pathologic conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods, or duration of administration or application, in such manner and form, as are necessary for the protection of users".

24. That pursuant to § 502(j) of 52 Stat 1040, a drug is deemed misbranded if it is "dangerous to health when used in the dosage, or with the frequency of duration prescribed, recommended or suggested in the labeling thereof".

25. That the promotion of said drug, Bendectin, by the Defendant for the use in females during the time period in controversy, without revealing or attempting to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug, constituted misbranding of said pharmaceutical drug per sub-sections (a), (f)(2) and (j) of § 502 and (n) of § 201 of 52 Stat 1040.

26. That violation of said Federal Statutes in the promotion of said drug, Bendectin, by the Defendant herein enumerated, constitutes a rebuttable presumption of negligence.

27. That the Defendant's violation of said Federal Statutes directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson, a Minor, were and will be caused to incur considerable medical

and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Larry James Christopher Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

FIFTH CAUSE OF ACTION

28. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 27 and for their Fifth Cause of Action state as follows.

29. The Defendant has made false and fraudulent representations of fact as to the safety, nontoxicity, and freedom from side effects of its product Bendectin and those representations were made under circumstances that the said Defendant knew or should have known that they were false, or alternatively, were represented to be true while said Defendant had no knowledge as to the truth thereof and the said Defendant stood to benefit financially by its misrepresentations, active and constructive. These representations were made in promotional literature, product inserts and by detailmen to prescribing physicians. By these representations the Defendant worked a fraud and deceit upon the consuming public, and more particularly, upon the Plaintiffs.

30. The Defendant deliberately pursued a policy of non-disclosure with regard to adverse reactions attributable to the product Bendectin, especially, but not limited to, a number of reporting physicians, each reporting that a number of mothers who used Bendectin during pregnancy gave birth to physically deformed babies. The said Defendant thereby deprived the medical community and the public and the Plaintiffs of significant facts which, if known, would have

permitted an informed judgment of the drug in light of the grave risks attending its use.

31. The Defendant failed to submit all relevant data bearing on the safety of the drug Bendectin to the Food and Drug Administration, as required by law.

32. That the acts and omissions of the Defendant, as aforementioned, directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment; and Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Larry James Christopher Thompson, Individually, had been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

SIXTH CAUSE OF ACTION

33. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 32 and for their Sixth Cause of Action state as follows.

34. The foregoing acts and omissions of the Defendant were willful, wanton and grossly negligent and caused, directly and proximately, the injuries to Plaintiffs as aforementioned, all to which Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Twenty Two Million Five Hundred Thousand (\$22,500,000.00) Dollars

punitive damages; Plaintiff Larry James Christopher Thompson, Individually, has been damaged in the amount of Ten Million (\$10,000,000.00) Dollars punitive damages; and Plaintiff Donna Lynn Thompson, Individually, has been damaged in the amount of Ten Million (\$10,000,000.00) Dollars punitive damages.

WHEREFORE, Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, demand Judgment against the Defendant in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages and Twenty Two Million Five Hundred Thousand (\$22,500,000.00) Dollars punitive damages; Plaintiff Larry James Christopher Thompson, Individually, demands Judgment against the Defendant in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages and Ten Million (\$10,000,000.00) Dollars punitive damages; and Plaintiff Donna Lynn Thompson, Individually, demands Judgment against the Defendant in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages and Ten Million (\$10,000,000.00) Dollars punitive damages. Plaintiffs also demand all costs, interest and attorneys fees, and all other relief to which they may be entitled.

WAITE, SCHNEIDER, BAYLESS
& CHESLEY CO., L.P.A.

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 Suite 503
 Washington, D.C. 20005
 CO-COUNSEL FOR PLAINTIFFS

JURY DEMAND

The Plaintiffs herein demand a trial by jury on all issues.

/s/ Stanley M. Chesley
 TRIAL COUNSEL FOR
 PLAINTIFFS.

COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO.

Case No. A8307057

Neil Frazer MacTavish and Margaret MacTavish as Next
 Friends and Guardians of Neil MacTavish, A Minor
 49 Bells Burn Avenue, LinLithgow, Scotland

Neil Frazer MacTavish, Individually
 49 Bells Burn Avenue, LinLithgow, Scotland

Margaret MacTavish, Individually
 49 Bells Burn Avenue, LinLithgow, Scotland
 Plaintiffs,

v.

Merrell-Dow Pharmaceuticals, Inc., (formerly known as
 Richardson-Merrell, Inc.) a Delaware Corporation
 2110 East Galbraith Road, Cincinnati, Ohio 45215
 Defendant.

COMPLAINT AND JURY DEMAND

[Filed September 1, 1983]

Now come the Plaintiffs, Neil Frazer MacTavish and
 Margaret MacTavish as Next Friends and Guardians of Neil
 MacTavish, a Minor, and Individually, and state their causes
 of action as follows.

FIRST CAUSE OF ACTION

1. The Plaintiffs, Neil Frazer MacTavish and Margaret
 MacTavish, as Next Best Friends and Guardians of Neil Mac-
 Tavish, a Minor, and Individually, state that they are
 residents of the City of LinLithgow, Country of Scotland.

2. That Defendant Merrell-Dow Pharmaceuticals, Inc.,
 FDBA Merrell-National Laboratories, Division of Richard-

son-Merrell, Inc., is a Delaware corporation with its principal place of business in the City of Cincinnati, County of Hamilton, State of Ohio.

3. That on or about August of 1978, Plaintiff Margaret MacTavish became pregnant with Neil MacTavish.

4. That during the first trimester of said pregnancy, Margaret MacTavish began to experience nausea for which her obstetrician prescribed the drug product known as Bendectin.

5. That said product, Bendectin, is a prescription drug made and distributed by the Defendant.

6. That Neil MacTavish was born May 11, 1979 subsequent to which it became obvious that the minor suffered from multiple deformities, including but not limited to, complete absence of the right hand; both forearm bones are present, but there are no definite carpals.

7. That as a result of said abnormalities, Neil MacTavish was caused to undergo extensive medical treatment and was and will continue to be required to undergo further medical treatment.

8. That the injuries suffered by Neil MacTavish were directly and proximately caused by the administration of the drug product Bendectin to Margaret MacTavish during the first trimester of pregnancy.

9. That the negligence of the Defendant in developing, marketing, producing, manufacturing, distributing and selling a product that Defendant knew or should have known could cause injuries and defects in children such as Neil MacTavish upon ingestion during pregnancy, directly and proximately caused said injuries; that the injuries were directly and proximately caused by the negligence of the Defendant in failing to test or inadequately testing the potential birth defect producing effects upon ingestion of Bendectin during pregnancy; that injuries were caused, directly and proximately by the negligence of the Defendant in failing to warn the users of Bendectin of the potential birth defect producing effects upon ingestion during pregnancy.

10. That as a direct and proximate result of the

aforementioned negligence of the Defendant, Neil MacTavish was and will be caused to suffer considerable pain and suffering and to undergo further medical treatment, and Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff, Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

SECOND CAUSE OF ACTION

11. The plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 10 and for their Second Cause of Action state as follows.

12. That Defendant expressly and impliedly warranted that its product, Bendectin, was of merchantable quality and fit and safe for its intended purposes and uses.

13. That Defendant breached said express and implied warranties of merchantability, fitness and safety and that said breach directly and proximately caused the injuries suffered by Neil MacTavish, a Minor, and that as a direct and proximate breach of the aforementioned warranties, said Minor was and will be caused to suffer considerable pain and suffering, and to undergo continuous medical treatment, and Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish were and will be caused to suffer considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory

damages; Plaintiff, Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff, Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

THIRD CAUSE OF ACTION

14. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 13 and for their Third Cause of Action state as follows.

15. That Defendant is strictly liable in that it developed, marketed, produced, manufactured, distributed and sold an inherently dangerous and defective drug, to-wit Bendectin, which it knew or should have known could cause injuries and defects in children such as said Minor upon ingestion during pregnancy, while failing to test or inadequately testing the potential birth defect producing effects upon ingestion during pregnancy and failing to warn the users of Bendectin of the potential birth defect producing effects upon ingestion during pregnancy.

16. That the foregoing acts and omissions of the Defendant directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

FOURTH CAUSE OF ACTION

17. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 16 and for their Fourth Cause of Action state as follows.

18. That the applicable Federal law covering the manufacturing and distributing of drugs during the time period in controversy was the Federal Food, Drug and Cosmetics Act passed by the 7th Congress on June 25, 1938, and cited as 52 Stat 1040, as amended.

19. That the purpose of 52 Stat 1040, among other purposes, was to prohibit the movement in Interstate Commerce of misbranded drugs.

20. That per § 201(n) of 52 Stat 1040, the determination as to whether a drug is misbranded includes "not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences, which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary and usual".

21. That Defendant did not at any time during the time period in controversy, reveal or attempt to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug in question for indications relating to pregnancy.

22. That pursuant to § 502(a) of 52 Stat 1040, a drug is deemed misbranded if its labeling is false or misleading in any particular.

23. That pursuant to § 502(f)(2) of 52 Stat 1040, a drug is deemed misbranded unless its labeling bears "such adequate warning against use in those pathologic conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods, or duration of administration or application, in such manner and form, as are necessary for the protection of users".

24. That pursuant to § 502(j) of 52 Stat 1040, a drug is deemed misbranded if it is "dangerous to health when used in the dosage, or with the frequency of duration prescribed, recommended or suggested in the labeling thereof".

25. That the promotion of said drug, Bendectin, by the Defendant for the use in females during the time period in controversy, without revealing or attempting to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug, constituted misbranding of said pharmaceutical drug per sub-sections (a), (f)(2) and (j) of § 502 and (n) of § 201 of 52 Stat 1040.

26. That violation of said Federal Statutes in the promotion of said drug, Bendectin, by the Defendant herein enumerated, constitutes a rebuttable presumption of negligence.

27. That the Defendant's violation of said Federal Statutes directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

FIFTH CAUSE OF ACTION

28. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 27 and for their Fifth Cause of Action state as follows.

29. The Defendant has made false and fraudulent representations of fact as to the safety, nontoxicity, and freedom from side effects of its product Bendectin and those representations were made under circumstances that the said Defendant knew or should have known that they were false, or alternatively, were represented to be true while said Defendant had no knowledge as to the truth thereof and the said Defendant stood to benefit financially by its misrepresentations, active and constructive. These representations were made in promotional literature, product inserts and by detailmen to prescribing physicians. By these representations the Defendant worked a fraud and deceit upon the consuming public, and more particularly, upon the Plaintiffs.

30. The Defendant deliberately pursued a policy of non-disclosure with regard to adverse reactions attributable to the product Bendectin, especially, but not limited to, a number of reporting physicians, each reporting that a number of mothers who used Bendectin during pregnancy gave birth to physically deformed babies. The said Defendant thereby deprived the medical community and the public and the Plaintiffs of significant facts which, if known, would have permitted an informed judgment of the drug in light of the grave risks attending its use.

31. The Defendant failed to submit all relevant data bearing on the safety of the drug Bendectin to the Food and Drug Administration, as required by law.

32. That the acts and omissions of the Defendant, as aforementioned, directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compen-

satory damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

SIXTH CAUSE OF ACTION

33. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 32 and for their Sixth Cause of Action state as follows.

34. The foregoing acts and omissions of the Defendant were willful, wanton and grossly negligent and caused, directly and proximately, the injuries to Plaintiffs as aforementioned, all to which Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Twenty Two Million Five Hundred Thousand (\$22,500,000.00) Dollars punitive damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Ten Million (\$10,000,000.00) Dollars punitive damages; and Plaintiff Margaret MacTavish, Individually, has been damaged in the amount of Ten Million (\$10,000,000.00) Dollars punitive damages.

WHEREFORE, Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, demand Judgment against the Defendant in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages and Twenty Two Million Five Hundred Thousand (\$22,500,000.00) Dollars punitive damages; Plaintiff Neil Frazer MacTavish, Individually, demands Judgment against the Defendant in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages and Ten Million (\$10,000,000.00) Dollars punitive damages; and Plaintiff Margaret MacTavish, Individually, demands Judgment against the Defendant in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages and Ten

Million (\$10,000,000.00) Dollars punitive damages. Plaintiffs also demand all costs, interest and attorneys fees, and all other relief to which they may be entitled.

WAITE, SCHNEIDER, BAYLESS
& CHESLEY CO., L.P.A.

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Washington, D.C. 20005
CO-COUNSEL FOR PLAINTIFFS

JURY DEMAND

The Plaintiffs herein demand a trial by jury on all issues.

/s/ STANLEY M. CHESLEY
TRIAL COUNSEL FOR PLAINTIFFS

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Case No. A 8307058

[Title omitted in Printing]

PETITION FOR REMOVAL

(Filed September 8, 1983)

The Petitioner Merrell Dow Pharmaceuticals Inc., hereby petitions this Court for removal of the above-entitled action from the Court of Common Pleas of Hamilton County, Ohio, to the United States District Court for the Southern District of Ohio, and respectfully states as follows:

1. That the Petitioner, Merrell Dow Pharmaceuticals Inc., is the defendant in a civil action commenced against it on September 1, 1983, in the Court of Common Pleas of Hamilton County, Ohio, entitled: "Larry James Christopher Thompson and Donna Lynn Thompson as Next Friends and Guardians of Jessica Elizabeth Thompson, et al., Plaintiffs, against Merrell Dow Pharmaceuticals Inc., (formerly known as Richardson-Merrell, Inc.), Defendant." A copy of the Complaint and Jury Demand in that action are attached hereto.

2. That the above-described action is one of which this Court has original jurisdiction under the provisions of Title 28, *United States Code*, Section 1332, and is one which may be removed to this Court by the Petitioner, defendant herein, pursuant to the provisions of Title 28, *United States Code*, Section 1441, in that it is a civil action wherein the matter in controversy exceeds the sum or value of \$10,000 exclusive of interest and costs, and is between citizens of a State and citizens or subjects of a foreign state, and is founded, in part,

on an alleged claim arising under the laws of the United States: The plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson at the time this action was commenced, were and still are citizens of Ontario, Canada, and the defendant, Merrell Dow Pharmaceuticals Inc., at the time this action was commenced, was and still is a corporation incorporated under the laws of the State of Delaware, with its principal place of business in the State of Ohio; Plaintiffs' Fourth Cause of Action alleges that defendant violated provisions of a federal statute, the Federal Food, Drug, and Cosmetics Act, cited as 52 Stat. 1040, §§ 502(a), (f)(2) & (j) and 201(n).

3. Petitioner files herewith a bond with good and sufficient surety in the sum of Two Hundred Fifty Dollars (\$250.00) conditioned as provided by Title 28, *United States Code*, Section 1446(d), that Petitioner will pay all costs and disbursements by reason of the removal proceedings hereby brought should it be determined that this action is not removable or is improperly removed.

WHEREFORE, Petitioner prays that the above-described attempted action against it in the Court of Common Pleas of Hamilton County, Ohio be removed therefrom to this Court.

Dated: September 7, 1983

Frank C. Woodside, III
2100 Fountain Square Plaza
511 Walnut Street
Cincinnati, Ohio 45202
(513) 621-6747
Trial Counsel for Defendant,
Merrell Dow Pharmaceuticals Inc.

OF COUNSEL:
DINSMORE & SHOHL
Christine L. McBroom

AFFIDAVIT OF FRANK C. WOODSIDE, III

STATE OF OHIO :
 : SS:
 COUNTY OF HAMILTON :

Frank C. Woodside, III, being duly sworn, deposes and says:

1. I am the attorney for the Petitioner herein, MERRELL DOW PHARMACEUTICALS INC., a Delaware corporation.

2. I have read the foregoing PETITION FOR REMOVAL and am informed and believe that the matters stated therein are true and on that ground allege them to be true.

Executed this 7th day of September, 1983 at Cincinnati, Ohio.

/s/ FRANK C. WOODSIDE, III

[Jurat Omitted in printing]

[Certificate of Service omitted in printing]

**UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF OHIO
 WESTERN DIVISION**

Case No. A 8307057

[Title omitted in Printing]

PETITION FOR REMOVAL

(Filed September 8, 1983)

The Petitioner Merrell Dow Pharmaceuticals Inc., hereby petitions this Court for removal of the above-entitled action from the Court of Common Pleas of Hamilton County, Ohio, to the United States District Court for the Southern District of Ohio, and respectfully states as follows:

1. That the Petitioner, Merrell Dow Pharmaceuticals Inc., is the defendant in a civil action commenced against it on September 1, 1983, in the Court of Common Pleas of Hamilton County, Ohio, entitled: "Neil Frazer MacTavish and Margaret MacTavish as Next Friends and Guardians of Neil MacTavish, et al., Plaintiffs, against Merrell Dow Pharmaceuticals Inc., (formerly known as Richardson-Merrell, Inc.), Defendant." A copy of the Complaint and Jury Demand in that action are attached hereto.

2. That the above-described action is one of which this Court has original jurisdiction under the provisions of Title 28, *United States Code*, Sections 1332, and is one which may be removed to this Court by the Petitioner, defendant herein, pursuant to the provisions of Title 28, *United States Code*, Section 1441, in that it is a civil action wherein the matter in controversy exceeds the sum or value of \$10,000 exclusive of interest and costs, and is between citizens of a State and citizens or subjects of a foreign state, and is founded, in part, on an alleged claim arising under the laws of the United

States: The plaintiffs, Neil Frazer MacTavish and Margaret MacTavish at the time this action was commenced, were and still are citizens or subjects of the Country of Scotland, and the defendant, Merrell Dow Pharmaceuticals Inc., at the time this action was commenced, was and still is a corporation incorporated under the laws of the State of Delaware, with its principal place of business in the State of Ohio; Plaintiffs' Fourth Cause of Action alleges that defendant violated provisions of a federal statute, the Federal, Food, Drug, and Cosmetics Act, cited as 52 Stat. 1040, §§ 502(a), (f)(2) & (j) and 201(n).

3. Petitioner files herewith a bond with good and sufficient surety in the sum of Two Hundred Fifty Dollars (\$250.00) conditioned as provided by Title 28, *United States Code*, Section 1446(d), that Petitioner will pay all costs and disbursements by reason of the removal proceedings hereby brought should it be determined that this action is not removable or is improperly removed.

WHEREFORE, Petitioner prays that the above-described attempted action against it in the Court of Common Pleas of Hamilton County, Ohio be removed therefrom to this Court.

Dated: September 7, 1983.

/s/ FRANK C. WOODSIDE, III
2100 Fountain Square Plaza
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(513) 621-6747
Trial Counsel for Defendant,
Merrell Dow Pharmaceuticals, Inc.

OF COUNSEL:
DINSMORE & SHOHL
Christine L. McBroom

AFFIDAVIT OF FRANK C. WOODSIDE, III

STATE OF OHIO

: SS:

COUNTY OF HAMILTON :

Frank C. Woodside, III, being duly sworn, deposes and says:

1. I am the attorney for the Petitioner herein, MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation.

2. I have read the foregoing PETITION FOR REMOVAL and am informed and believe that the matters stated therein are true and on that ground allege them to be true.

Executed this 7th day of September, 1983 at Cincinnati, Ohio.

/s/ FRANK C. WOODSIDE, III

[Jurat Omitted in printing]

[Certificate of Service omitted in printing]

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Civil Action No. A-8307057

[Title omitted in printing]

**PLAINTIFFS' MOTION TO REMAND
UNDER § 1447(c) FOR LACK OF JURISDICTION**

(Filed October 14, 1983)

COME NOW the plaintiffs, by counsel, and on the basis more fully explained in the accompanying Memorandum in Support hereof, move this Court for an order remanding the above-captioned actions to the Court of Common Pleas for Hamilton County, Ohio.

Respectfully submitted,

WAITE, SCHNEIDER, BAYLESS
& CHESLEY

By: /s/ JEROME L. SKINNER
(S547)

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/s/ GEORGE A. KOKUS, ESQ.
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/s/ ALLEN T. EATON, ESQ.
ALLEN T. EATON &
ASSOCIATES
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Washington, D.C. 20005
Counsel for Plaintiffs

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Civil Action No. A-8307057

[Title omitted in printing]

**MEMORANDUM IN SUPPORT OF
PLAINTIFFS' MOTION TO REMAND
UNDER § 1447(c) FOR LACK OF JURISDICTION**
(Filed October 14, 1983)

I. Procedural History

Plaintiffs, residents of Scotland, filed the subject actions on September 1, 1983, in the Court of Common Pleas in Hamilton County, Ohio. On or about September 7, 1983, defendant filed a removal petition in this Court with the requisite bond. Plaintiffs, through this motion, seek an order under 28 U.S.C. § 1447(c) remanding the actions to the state court and requiring the defendants to pay plaintiffs, in accordance with 28 U.S.C. § 1446, costs and disbursements incurred by reason of the removal proceedings.

II. Operative Facts

Plaintiffs are residents of Scotland, United Kingdom, who allege that their children suffered birth defects as the result of the ingestion of Debendox during pregnancy. Debendox is the British trade name for the antinauseant morning sickness drug Bendectin manufactured by defendant Merrell. Plaintiffs allege, *inter alia*, that defendant Merrell violated certain provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. § 301-*et seq.* (52 Stat. 1040-*et seq.*)¹

¹ Case numbers are A83-07057 and A83-07058. Copies of the complaints are attached hereto and incorporated herewith by reference to defendant's removal petition (Exhibit A).

In their Fourth Cause of Action, plaintiffs allege that defendant violated 21 U.S.C. § 352 when it sold Debendox (a/k/a Bendectin) in a branded and defective condition. Plaintiffs allege in paragraph 26 of their complaints that Merrell's violation of the Food, Drug and Cosmetic Act in promoting of Debendox constituted a rebuttable presumption of negligence.²

Defendants suggest that by asserting violations of the Food, Drug and Cosmetic Act, plaintiffs' claims arise under the laws of the United States, and thereby give this Court original jurisdiction under 28 U.S.C. § 1331 and provide the basis for removal under 28 U.S.C. § 1441(b).

III. Issues Presented

- A. Do plaintiffs' claims arise under the laws of the United States in the sense of 28 U.S.C. § 1331?
- B. Are there any other legally cognizable grounds for removal?
- C. Should the cases be removed?

IV. Discussion

- A. Allegations made in plaintiff's complaints do not provide a basis for federal question jurisdiction under 28 U.S.C. § 1331.

² Under Ohio law, violation of a safety statute is negligence *per se*, rendering the actor liable to plaintiff if his negligence caused or contributed to causing the plaintiff's injury. Plaintiffs will amend their complaint to include this allegation.

See *Freeman v. United States*, 509 F.2d 626 (6th Cir. 1975), in which the court held that when an injury is caused by an action which violates a safety statute, which is of the kind that the statute was intended to prevent, the action constitutes negligence *per se*.

See also *Shroades v. Rental Homes, Inc.*, 68 Ohio St.2d 20, 427 N.E.2d 774 (1981); *Zehe v. Falkner*, 26 Ohio St.2d 258, 271 N.E.2d 276 (1972). Both of these cases make clear that in Ohio it is a well-settled principle of law that a violation of a specific safety statute constitutes negligence *per se*.

In asking the Court to recognize the Food, Drug and Cosmetic Act as establishing the standard of care required of a drug manufacturer, federal jurisdiction is not vested in this Court under 28 U.S.C. § 1331. In the instant case, unlike *Cort v. Ash*, 422 U.S. 66 (1975) (private right of action principles set forth by Court) plaintiffs do not assert a federal statute as the jurisdictional basis for their claims, nor do they assert that their claims arise under the federal Food, Drug and Cosmetic Act.

Moreover, it is clear that the Act does not create a private right of action. In fact, defendant has argued in open court that there is no private right of action:

MR. LEECH: Your Honor, because there's no private right of action under the statute they are citing, and the cases so hold you can't recover damages as an individual plaintiff for the violation of the statute. The only person that can bring an action for violation of this statute is the U.S. Attorney's office.

THE COURT: What statute?

MR. LEECH: The Federal Drug & Cosmetic Act, and the section on which the plaintiff relies, regardless what they prove, they can't recover under the statute as a separate cause of action.

Oxendine v. Richardson-Merrell, Inc., No. 1245-82 (Superior Ct., District of Columbia, Transcript May 2, 1983, pp. 147-48) (Exhibit B).

Similarly, in the *Koller* case, defendant argued that there was no private right of action under the Food, Drug and Cosmetic Act. Defendant wrote in its Memorandum in Support of Partial Summary Judgment:

Moreover, the law is clear that there is no private cause of action under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* See, e.g., *Pacific Trading Co. v. Wilson and Co.*, 547 F.2d 367, 368 (7th Cir. 1976); *Orthopedic Equipment Co. v. Eustler*, 276 F.2d 455, 460 (4th Cir. 1960); *Keil v. Eli Lilly & Co.*, 490 F.Supp. 479

(E.D.Mich. 1980); *Gelley v. Astra Pharmaceutical Products, Inc.*, 466 F.Supp. 182, 186-187 (D.Minn. 1979), *aff'd* 610 F.2d 558 (9th Cir. 1979); *State of Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 F.Supp. 364, 365-366 (S.D.Fla. 1971); *Cross v. Board of Supervisors of San Mateo County*, 326 F.Supp. 634, 638 (N.D.Cal. 1968), *aff'd* 442 F.2d 362 (9th Cir. 1971); *Clairol, Inc. v. Suburban Cosmetics and Beauty Supply, Inc.*, 278 F.Supp. 859, 860-861 (N.D.Ill. 1968).

Koller, et al. v. Richardson-Merrell, Inc., No. 80-1258 (U.S. District Court for the District of Columbia, Memorandum of Defendant Richardson-Merrell, Inc. In Support of Its Motion for Partial Summary Judgment Dismissing Plaintiffs' Claims for Fraud and Punitive Damages, February 5, 1982 at p. 42).

Plaintiffs' actions, to be sure, do not arise under federal law, as they do not assert a federally-created cause of action. Plaintiffs only urge that the federal Food, Drug and Cosmetic Act embodies the appropriate *standard of care* to be employed by the Ohio Court in determining if Merrell has been negligent, or if Bendectin is a defective product.

This principle of law regarding negligence *per se* has long been adopted by the courts in Ohio, and is indeed the majority rule. W. Prosser, *Law of Torts*, § 36 (4th ed. 1971); *Restatement (Second) of Torts*, §§ 285, 286, 288B; and 39 O. Jur2d Negligence §§ 43-44 (1959).

In a recent Pennsylvania case, the United States Court of Appeals for the Third Circuit, in applying Pennsylvania law that is nearly identical to the law of Ohio on negligence *per se*, held as follows:

"Under Pennsylvania law, the violation of a governmental safety regulation constitutes negligence *per se*" if the regulation "was, in part, intended to protect the interest of another as an individual [and] the interest of the plaintiff which was invaded . . . was one which the act intended to protect. Astra cannot seriously dispute that section 130.35 [of the Code of Federal Regulations implementing provisions of the Food, Drug and Cosmetic

Act] was promulgated to protect individuals such as Harrikah Stanton from precisely the type of harm that here occurred — an unexpected adverse reaction to Xylocaine. It thus would appear that Astra's failure to file the reports constituted negligence *per se*.

Stanton v. Astra Pharmaceutical Products, Inc., Nos. 92-3364 and 82-3380 (3d Cir., Sept. 26, 1983, Slip Op. at 21-22) (citations omitted) (Exhibit C).

In summary, plaintiffs' claim that Merrell's violations of the federal Food, Drug and Cosmetic Act constitute negligence *per se* does not give rise to federal question jurisdiction under 28 U.S.C. § 1331. In the absence of federal question jurisdiction, there simply is no basis for removal under 28 U.S.C. § 1441.

Article III Courts have limited jurisdiction. In the absence of original subject matter jurisdiction in these cases, removal is improvident.

B. There is no other legally cognizable grounds for removal.

Defendant could contend that jurisdiction of this Court could be based on 28 U.S.C. § 1332. This argument, too, must fail. In *Pack v. Rich Terminal Company*, 502 F.Supp. 58 (S.D. Ohio 1980), Judge Spiegel held that if a defendant is a citizen of a state, removal from state court is improper.

Ohio is Merrell's principal place of business. Merrell is a corporate citizen of Ohio. Removal, therefore, is inappropriate under 28 U.S.C. § 1441(b).

After a careful review of the United States Code to discern any other bases for the exercise of jurisdiction by federal courts under the circumstances of this case, plaintiffs can find no colorable basis for the exercise of jurisdiction by an Article III Court.

C. The cases should be remanded to state court.

In the absence of original jurisdiction in the federal courts, there simply is no basis for removal. The cases, therefore,

should be remanded to state court. Finally, plaintiffs are entitled to the payment of costs and disbursements incurred because of these removal proceedings.

Respectfully submitted,
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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Case No. C-1-83-1436

Case No. C-1-83-1437

[Title omitted in printing]

**DEFENDANT MERRELL DOW PHARMACEUTICALS
INC.'S MEMORANDUM IN RESPONSE TO
PLAINTIFFS' MOTION TO REMAND**

(Filed October 31, 1983)

Defendant, Merrell Dow Pharmaceuticals Inc., (hereinafter "Merrell Dow"), hereby responds to "Plaintiffs' Motion to Remand Under § 1447(c) For Lack Of Jurisdiction" (hereinafter "Plaintiffs' Motion to Remand") the two foreign plaintiff actions (Thompson and MacTavish) originally filed in the Hamilton County, Ohio Court of Common Pleas on September 1, 1983 and removed to this Court, pursuant to 28 U.S.C. § 1446(b), by way of a Petition to Remove filed September 7, 1983.

I. FACTUAL BACKGROUND.

Plaintiffs have also set forth the "Operative Facts" for these cases: The *MacTavish* Plaintiffs are residents of Scotland and allege in their Complaint that the infant plaintiff suffered birth defects as a result of his mother's ingestion of Debendox during pregnancy. The *Thompson* Plaintiffs are residents of Ontario, Canada and allege that the infant plaintiff suffered birth defects as a result of his mother's ingestion of Bendectin during pregnancy.

Plaintiffs have alleged violations of the federal Food, Drug

and Cosmetic Act, 21 U.S.C. §§ 201(n) and 502(a), (f)(2) and (j), in Paragraph 25 of their Complaints and claim that these violations of a federal statute constitute a rebuttable presumption of negligence.¹

II. ARGUMENT.

A. Plaintiffs Are Merely Attempting To Circumvent This Court's Order Dismissing Similar Foreign Plaintiff Actions.

On August 24, 1982, this Court ordered the dismissal of twelve actions filed by foreign plaintiffs, all citizens of the United Kingdom.² These cases were dismissed on grounds of *forum non conveniens* and are on appeal to the United States Court of Appeals for the Sixth Circuit.³ Several motions to dismiss cases filed by additional foreign plaintiffs are presently pending before this Court.⁴ In these motions Merrell Dow

¹ In their Motion to Remand, Plaintiffs argue that under Ohio substantive law, this violation of a federal statute is "negligence *per se*." (Plaintiffs' Motion to Remand, n. 2). Merrell Dow does not wish to address issues irrelevant to the present controversy, however it feels compelled to discuss the issue raised concerning negligence *per se*. As argued in all foreign plaintiff cases in which Merrell Dow has filed Motions to Dismiss on grounds of *forum non conveniens*, a proper interpretation of Ohio choice-of-law rule dictates that both a federal court sitting in Ohio and the Ohio court itself would apply the laws of Scotland and Ontario, Canada to the issues of alleged negligence. Therefore, Ohio law regarding negligence *per se* would not be the authority upon which either Court would rely.

² Order and Judgment Granting Defendant's Motions To Dismiss, *Keith Neil Alexander, et al. v. Richardson-Merrell, Inc.*, and eleven other cases, Case Nos. C-1-82-285; 286; 287; 288; 289; 290; 291; 292; 293; 294; 295; and 310.

³ *Steven Thomas Dowling, et al. Plaintiffs/Appellants, v. Richardson-Merrell, Inc.*, Defendant/Appellee, Consolidated Case Nos. 82-3617 through 82-3628. Oral argument is scheduled for November 30, 1983.

⁴ *Allan Alexander Watson, et al. v. Merrell Dow Pharmaceuticals, Inc.*, *et al.* and five similarly situated cases, S.D. Ohio, Case Nos. C-1-82-327; 469; 607; 608; 609; and 611; *Peter Stewart, et al. v. Richardson-Merrell,*

has urged the Court to dismiss the cases on grounds of *forum non conveniens*, and asked this Court to adopt the same reasoning it utilized in dismissing the first twelve foreign plaintiff cases.

Merrell Dow believes that Plaintiffs in the two cases involved in these remand proceedings are attempting to circumvent the effect of this Court's Order dismissing the twelve *Alexander* cases. Plaintiffs have filed these actions in an Ohio state court in anticipation that the Sixth Circuit will affirm the *Alexander* dismissals, and upon the further expectation that this Court will similarly dismiss all foreign plaintiff cases filed against Merrell Dow where an alternative forum exists in which to more properly litigate the disputes.

B. Merrell Dow Removed These Cases On Grounds Of Federal Question Jurisdiction, Not On Grounds Of Diversity Of Citizenship.

Plaintiffs have moved to remand these cases to the state court arguing that removal under 28 U.S.C. § 1446(b) upon grounds of diversity of citizenship is improper if the defendant is a citizen of the state. Merrell Dow does not contest the impropriety of removal of these cases to this Court based solely on grounds of diversity of citizenship.⁵ However, the case which Plaintiffs cite as support for this argument does not apply to the basis for removal upon which Merrell Dow petitioned this Court, to wit: federal question jurisdiction.

Inc., S.D. Ohio, Case No. C-1-82-426; *Vicki Elizabeth Crallan, et al. v. Merrell Dow Pharmaceuticals, Inc.*, S.D. Ohio, Case No. C-1-82-590; *Gordon Foorte Peter Vandervliet, et al. v. Merrell Dow Pharmaceuticals, Inc.*, S.D. Ohio, Case No. C-1-82-470.

⁵ A reading and interpretation of 28 U.S.C. § 1441(a) & (b) make it clear that because Merrell Dow is a "citizen" of Ohio, in that it has its principal place of business in Reading, Hamilton County, Ohio, 28 U.S.C. § 1332(c), removal to this Court would not be proper based solely upon a diversity of citizenship basis. Merrell Dow was cognizant of the law in this Circuit when it filed the Petitions For Removal in these cases. *Jacobs & Co. Levin*, 86 F.Supp. 850 (N.D. Ohio 1949), *aff'd.*, 180 F.2d 356 (6th Cir. 1950).

The defendant in *Pack v. Rich Terminal Company*, 502 F. Supp. 58 (S.D. Ohio 1980), cited at page 6 of Plaintiffs' Motion to Remand, had petitioned the Court for removal alleging "federal jurisdiction based *only* on the basis of diversity. . . ." *Id.* at 59 (emphasis added). However, Merrell Dow did not petition the Court for removal based *only* on grounds of diversity of citizenship of the parties; Merrell Dow petitioned the Court to remove these cases on grounds that each Plaintiff's Fourth Cause of Action is one of which this Court has original jurisdiction, as it alleged a claim arising under the laws of the United States, and was therefore removable pursuant to 28 U.S.C. § 1441.

C. If In Fact Plaintiffs Do Not Intend On Litigating Alleged Violations Of the Federal Food, Drug And Cosmetic Act In State Court, Merrell Dow Concedes That No Federal Question Exists In These Actions.

It is a well-established rule of law "that federal questions in removal cases must be disclosed on the face of the *plaintiff's* complaint and must be essential to the plaintiff's cause of action. . . ." *Border City Savings & Loan Assn. v. Kennebec Mortgage & Equities, Inc.*, 523 F. Supp. 190, 192 (S.D. Ohio 1981) (original emphasis). "[I]t is the rule that to justify removal to the federal court the controlling federal question must appear directly and positively upon the complaint." *Venner v. New York Central Railroad Co.*, 203 F. 373, 374 (6th Cir. 1923). See, also, *Gully v. First National Bank in Meridian*, 299 U.S. 109, 112-13 (1936); *First National Bank of Aberdeen v. Aberdeen National Bank*, 627 F.2d 843, 849 (8th Cir. 1980); *Mountain Fuel Supply Co. v. Johnson*, 586 F.2d 1375, 1380 (10th Cir. 1978).

Plaintiffs' Fourth Causes of Action evidence a substantial federal question regarding interpretation, application, and alleged violations of the federal Food, Drug and Cosmetic Act. Indeed, the Complaints demand the right of each infant plaintiff to be compensated in the amount of \$10,000,000.00

(ten million dollars), and the right of each parent plaintiff to be compensated \$5,000,000.00 (five million dollars) for these alleged violations. This federal question appears "directly and positively" upon each of the Complaints. Therefore, Merrell Dow was completely justified in petitioning this Court to remove these cases from the state court.

Plaintiffs have moved to remand these two cases on grounds that, contrary to the allegations stated in the Fourth Causes of Action in their Complaints, the alleged violations of the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, do not give rise to a federal question so as to confer jurisdiction upon this Court. Plaintiffs argue that they are not suing Merrell Dow *under* federal law and are not asserting that a federal law is the *basis* for their claims.

"Plaintiffs' actions, to be sure, do not arise under federal law, as they do not assert a federally-created cause of action. Plaintiffs only urge that the federal Food, Drug and Cosmetic Act embodies the appropriate *standard of care* to be employed by the Ohio Court in determining if Merrell has been negligent, or if Bendectin is a defective product."

(Plaintiffs' Motion to Remand, pg. 5, original emphasis). If Plaintiffs do not intend on litigating the issues concerning allegations that Merrell Dow violated the reporting requirements of the federal Food, Drug and Cosmetic Act in a state court action, then Merrell Dow concedes that, although clear from the face of the Complaints, no federal question jurisdiction exists in these cases.

Plaintiffs' counsel have, however, alleged federal question jurisdiction under 28 U.S.C. § 1331 in numerous Bendectin cases filed against Merrell Dow in federal district courts throughout the United States.⁶ Therefore, Merrell Dow is

⁶ See e.g., *Irving Rosenstein, et al., v. Merrell Dow Pharmaceuticals, Inc.*, S.D. Ohio Case No. C-1-82-964 (also a foreign plaintiff action); *Terry Lawson, et al.*, S.D. Ohio Case No. C-1-83-1370 (filed Aug. 31, 1983, one

justifiably confused: Will the federal question regarding the alleged violations of the Food, Drug and Cosmetic Act be argued *only* in the Bendectin cases presently pending before this Court, and abandoned in the state court? Merrell Dow doubts that Plaintiffs intend to abandon any claims they have asserted. Thus, Merrell Dow believes that the federal question, which is patently obvious upon a review of each Complaint, confers removal jurisdiction, pursuant to 28 U.S.C. §§ 1331 and 1441(a) & (b), upon this Court.

D. If Plaintiffs Do Not Intend On Abandoning Their Claims That Merrell Dow Violated Provisions Of The Federal Food, Drug And Cosmetics Act, Then It Is Clear That An Important Federal Question Exists In These Actions.

As discussed previously, the determination as to whether federal question jurisdiction exists in a removal action must be discerned from the face of the Complaint. A review of Plaintiffs' Complaints clearly reveals a claim arising under the laws of the United States. 28 U.S.C. §§ 1331 and 1441(b). "Arising under" jurisdiction exists when "a properly pleaded 'state-created' claim itself presents a 'pivotal question of federal law,' for example because an act of Congress must be construed or 'federal common-law govern[s] some disputed aspect' of the claim." *State of New York v. Citibank*, 537 F. Supp. 1192, 1196 (S.D.N.Y. 1982), quoting, *McFaddin Express, Inc. v. Adley Corp.*, 346 F.2d 424, 426 (2d Cir. 1965), cert. denied, 382 U.S. 1026 (1966). Moreover, "[t]he defendant is entitled to have the case removed to federal court . . . if plaintiff is attempting to avoid having an essentially federal claim adjudicated in a federal forum merely by artfully drafting the complaint in terms of state law." *People of the State of Illinois v. Kerr-McGee Chemical Corp.*, 677 F.2d 571, 575

day before the two instant actions were filed in the state court); *Terry Watson, et al. v. Merrell Dow Pharmaceuticals, Inc.*, S.D. Ohio Case No. C-1-83-47 (originally filed in the U.S. District Court for the Eastern District of Texas).

(7th Cir. 1981). See also *Mountain Fuel Supply Co. v. Johnson*, 586 F.2d 1375, (10th Cir. 1978) ("A case 'arises' under the laws of the United States if it clearly and substantially involves a dispute or controversy respecting the validity, construction or effect of such laws which is determinative of the resulting judgment." *Id.* at 1381. (citation omitted) (emphasis added)).

Even if the Court looks beyond the face of the Complaints to Plaintiffs' Motion to Remand, federal question jurisdiction exists — irrespective of Plaintiffs' arguments to the contrary. Although Plaintiffs state that they are not suing to *enforce* the provisions of the federal Food, Drug and Cosmetic Act, they allege, nevertheless, that Merrell Dow *violated* provisions of the Act. "A suit may arise under federal law, even though a federal remedy is not sought, if the plaintiff's claim relies substantially on propositions that define federal rights, duties or relationships." *Guinasso v. Pacific First Federal Savings And Loan Assn.*, 656 F.2d 1364, 1367 n. 7 (9th Cir. 1981).

Based upon the foregoing citations of authority, and upon Merrell Dow's suspicion that Plaintiffs will attempt to raise the alleged violations of a federal statute in the state court if the actions are remanded, it is submitted that this cause of action "arises under" the laws of the United States so as to confer upon this Court federal question jurisdiction pursuant to 28 U.S.C. §§ 1331 & 1441(b).⁷

E. The Court Should Not Award Plaintiffs Costs Incurred By Reason Of The Removal Proceedings.

Title 28 U.S.C. § 1446(c) permits a court to order the payment of costs if a case is improvidently removed from a state

⁷ Merrell Dow further submits that the remaining causes of action set forth in Plaintiffs' Complaints should be retained by this Court under pendent jurisdiction: The state and federal claims "derive from a common nucleus of operative fact," Plaintiffs "would ordinarily be expected to try them all in one judicial proceeding," and retention will accommodate "considerations of judicial economy, convenience and fairness to [the] litigants." *United Mine Workers of America v. Gibbs*, 383 U.S. 715, 725-26 (1966).

court. However, "while under the statute an award of costs against the removing party would appear to be discretionary with the district judge, courts are more inclined to assess costs when the nonremovability of the action is obvious." *Pack v. Rich Terminal Co.*, 502 F. Supp. 58 (S.D. Ohio 1980). As previously argued, the federal question upon which Merrell Dow petitioned this Court for removal is clearly stated on the face of Plaintiffs' Complaints. Merrell Dow was first made aware that Plaintiffs would argue that no federal question jurisdiction existed when it was served with Plaintiffs' Motion To Remand. Therefore, because removability is obvious from the Complaint, Merrell Dow submits that no costs should be awarded against it as a result of its filing with this Court the Petitions to Remove the *MacTavish* and *Thompson* cases.

IV. CONCLUSION.

For the reasons stated in this memorandum, Merrell Dow requests that the plaintiffs' Motion To Remand be overruled.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Case No. C-1-83-1436

Case No. C-1-83-1437

[Title omitted in printing]

**PLAINTIFFS' REPLY TO DEFENDANT MERRELL DOW
PHARMACEUTICALS, INC.'S MEMORANDUM
IN RESPONSE TO PLAINTIFFS' MOTION TO REMAND**

(Filed November 22, 1983)

Plaintiffs in the above-captioned cases hereby reply to defendant Merrell Dow Pharmaceuticals, Inc.'s response to plaintiffs' motion to remand.

Discussion

The sole basis upon which defendant opposes plaintiffs' motion to remand is that the lawsuits at issue "arise under" the laws of the United States within the meaning of the jurisdictional statute. 28 U.S.C. § 1331 (1980).

It is evident that the causes of action in these cases arise *not* under any law of the United States, but wholly under the common law. The defendant is an Ohio corporation and the rights claimed are those of parents and children who seek redress under the common law for injuries sustained from the ingestion of defendant's drug product Bendectin (Debendox). The foundation of plaintiffs' lawsuit turns upon duties and responsibilities imposed upon defendant under the laws of negligence, strict liability, fraud and implied and expressed warranty.

The Supreme Court has made it clear that for a suit to

"arise under" the laws of the United States that the laws of the United States must *create* part of the cause of action *by their own force*. *American Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257, 260 (1916) ("A suit arises under the law that creates the cause of action."); *Gully v. First National Bank in Meridian*, 299 U.S. 109, 112 (1936) (Federal question embraced if "a right or immunity created by the Constitution or laws of the United States [is] an element, and an essential one, of the plaintiff's cause of action.")

The mere reference to a federal statute as a criterion or test, when the law of the United States has no force of its own, does not suffice to establish that a cause of action arises under the laws of the United States. *Moore v. Chesapeake & Ohio Ry.*, 291 U.S. 205 (1934). In *Moore*, plaintiff alleged injuries received when he was involved in intrastate commerce and sought recovery under the Employers' Liability Act of Kentucky. Plaintiff, as part of his complaint under the Employers' Liability Act of Kentucky asserted violations of the Federal Safety Appliance Acts. In holding that plaintiff's complaint did *not* arise under the laws of the United States, and therefore was not cognizable in federal court, the Supreme Court wrote:

The Federal Safety Appliance Acts, while prescribing absolute duties, and thus creating correlative rights in favor of injured employees, did not attempt to lay down rules governing *actions for enforcing these rights* (emphasis added).

* * *

The Safety Appliance Acts having prescribed the duty in this fashion, the right to recover damages sustained by the injured employee through the breach of duty *sprang from the principle of the common law . . .* and was left to be enforced accordingly, or, in the case of the death of the injured employee, according to the applicable statute (emphasis added).

Id. at 215-16.

What defendant, however, fails to recognize is that the

Food, Drug & Cosmetic Act *does not create* substantive rights on behalf of plaintiffs in civil suits against drug manufacturers. Rather, it only serves as a yardstick for determining whether the manufacturer has satisfied the duty of reasonable care created under the common law of negligence.

Moreover, to suggest that the instant complaints reveal a pivotal "dispute or controversy respecting the validity, construction, or effect of [the Food, Drug & Cosmetic Act] upon the determination of which the result depends, *Shulthis v. McDougal*, 225 U.S. 561, 569 (1912),¹ is to read beyond the four corners of plaintiffs' complaint. The validity, construction, and/or effect of the Food, Drug & Cosmetic Act are *not* "pivotal" issues in this case; these cases allege causes of action for negligence, strict liability, fraud, and breach of implied and expressed warranties. The mere reference to a federal statute as a test or criterion does not suffice to establish that a cause of action arises under the laws of the United States, nor does it suffice to establish a pivotal dispute or controversy over the application of the Food, Drug & Cosmetic Act.

Moreover, plaintiffs' assertions that defendant has violated the Food, Drug & Cosmetic Act also can be viewed as merely replies in anticipation that defendant will raise as defenses its compliance with the provisions of the Act and the subsequent approval of the Food and Drug Administration for the marketing of Bendectin. Again, a federal question is not embraced in this instance. *Phillips Petroleum Co. v. Texaco, Inc.*, 415 U.S. 125, 127-28 (1974).

¹ The two cases primarily relied upon by defendant to support its position are both distinguishable from the instant cases. In *State of New York v. Citibank*, 537 F.Supp. 1192, 1196 (S.D.N.Y. 1982), the court found federal question jurisdiction where the complaint relied *exclusively* upon allegations of illegality under federal law. The complaint, in effect, sought to use state causes of action to litigate federal questions. The same cannot be said of the instant cases.

Similarly, to suggest that these cases involve *essentially federal claims* artfully drafted to avoid federal jurisdiction, *People of the State of Illinois v. Kerr-McGee Chemical Corp.*, 677 F.2d 571, 575 (7th Cir. 1981), is to misconstrue the nature of plaintiffs' complaints.

Conclusion

For the foregoing reasons, plaintiffs respectfully request the Court to remand these cases to the Court of Common Pleas for Hamilton County, Ohio.

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